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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,500	11/30/2001	Beth Anne Lange	KCC 4775 (K.C. No. 17,12	6529

321 7590 01/26/2005

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
KIDWELL, MICHELE M	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,500	LANGE ET AL.	
	Examiner	Art Unit	
	Michel Kidwell	3761	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the applicant has amended the claims to recite that the composition is suitable for ingestion by a suckling infant. The claimed language is not supported by the originally filed disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 – 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al. (US 5,281,186), and further in view of Allen (US 6,361,806).

With respect to claim 1, Buckley et al. (hereinafter "Buckley") discloses a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by a woman, the breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising a composition for improving breast and nipple skin care health which is suitable for ingestion by a suckling infant as set forth in col. 3, lines 28 – 35 and figures 1 and 3.

The difference between Buckley and claim 1 is the provision that the front side comprises 0.1g/m^2 to about 30 g/m^2 of a composition comprising omega-3 fatty acids.

Allen teaches a cream comprising an omega-3 fatty acid as set forth in col. 8, lines 23 – 26.

It would have been obvious to one of ordinary skill in the art to modify the breast pad of Buckley to provide the composition taught by Allen because while Buckley discloses that lotion of any type as is commercially available to afford protection and healing to an individual's skin portion may be provided on the breast cup arrangement (col. 3, lines 26 – 35), the composition of Allen promotes improvement of the skin as set forth in col. 7, line 64 to col. 8, line 6.

Additionally, it would have been obvious to one of ordinary skill of the art modify the amount of the composition used (i.e. 0.1g/m^2 to about 30 g/m^2) based on the size of the delivery vehicle (i.e. a large breast pad, a nipple pad, etc.) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only a level of ordinary skill in the art.

Regarding claims 2 – 3, 21 – 22, 36 – 37, 59 and 66, Allen teaches the claimed weight percentage of the omega 3 fatty acid as set forth in col. 12, lines 1 – 4.

Regarding claims 4 – 5 and 18 – 19, Allen teaches flaxseed oil as set forth in col. 28, lines 29 – 35.

With reference to claims 6, 24 and 42, Allen teaches vitamin C as set forth in col. 10, lines 13 – 17.

Regarding claims 7 – 8, 25 – 26, 43 – 44, 61, 65 and 68, Allen teaches the claimed pH as set forth in col. 10, lines 31 – 33.

As to claims 9, 27 and 45, Allen teaches a composition comprising 40% – 60% of a solidifying agent as set forth in col. 13, line 45 to col. 14, line 11.

With reference to claims 10, 11, 28, 29, 46 and 47, Allen teaches a composition comprising 1% – 40% of a fatty alcohol in the form of a sterol as set forth in col. 13, line 45 to col. 14, line 11.

As to claims 12, 30 and 48, Allen teaches the composition further comprising an extracted botanical as set forth in col. 14, lines 61 – 65.

It would have been obvious to one of ordinary skill in the art to modify the amount of extracted botanical used in the composition in order to achieve the desired product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

Regarding claims 13, 31 and 49, Allen teaches a composition comprising .01% – 10% of an emollient as set forth in col. 12, lines 1 – 3.

As to claims 14, 32 and 50, Allen teaches a composition comprising a viscosity enhancer as set forth in col. 10, lines 2 – 7.

It would have been obvious to one of ordinary skill in the art to modify the amount of viscosity enhancer used in the composition in order to achieve the desired product since it has been held that where the general conditions of a claim are disclosed in the

prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

Regarding claims 15, 33 and 51, Allen teaches a composition comprising a rheology enhancer a set forth in col. 15, lines 39 – 43.

It would have been obvious to one of ordinary skill in the art to modify the amount of rheology enhancer used in the composition in order to achieve the desired product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

Regarding claims 16, 34 and 52, Allen teaches a composition as a cream as set forth in col. 12, line 1.

With respect to claim 17, see the rejection of claim 1. Additionally, Allen teaches the use of an omega-6 fatty acid as set forth in col. 8, lines 19 – 22.

Regarding claim 20, Allen teaches the use of sunflower oil as set forth in col. 13, lines 55 – 60.

As to claims 23, 41, 57, 64 and 71, Allen teaches the ratio of omega-3 fatty acids to omega-6 fatty acids in the composition to be between 1:2 to about 2:4 as set forth in col. 19, table A.

With respect to claim 35, see the rejection of claims1 and 17. The examiner notes that linoleic acid, the omega-6 fatty acid disclosed by Allen, is considered an essential fatty acids.

With reference to claims 38 and 39, Allen teaches the claimed amount of essential fatty acids as set forth in col. 19, table A.

As to claim 40, Allen teaches the use of an omega-6 fatty acid as set forth in col. 19, table A.

With respect to claim 53, see the rejection of claims 1, 17 and 35. Additionally, Allen teaches a composition comprising from about 1% to about 15% of flaxseed oil as set forth in col. 13, lines 32 – 65.

As to claim 54, Allen teaches a composition comprising from about 1% to about 15% of flaxseed oil as set forth in col. 13, lines 32 – 65.

As to claim 55, Allen teaches a composition comprising from about 1% to about 15% of essential fatty acids as set forth in col. 13, lines 32 – 49.

With reference to claim 56, see the rejection of claims 1, 17, 35 and 53. Additionally, Allen teaches the composition including lenoleic acid as set forth in col. 8, lines 19 – 22.

With reference to claim 58, see the rejection of claims 1, 17, 35 and 53. The examiner contends that the claimed method steps would have resulted from the use of the device recited in claims 1, 17, 35 and 53.

As to claims 60 and 67, Allen teaches the claimed oil as set forth in col. 13, lines 55 – 67.

With respect to claims 62, 63, 69 and 70, Allen teaches a composition further including omega-6 fatty acids (i.e., essential fatty acids) in the form of linoleic acid as set forth in col. 19, table A.

With reference to claim 65, see the rejection of claims 1, 17, 35 and 53. The examiner contends that the claimed method steps would have resulted from the use of the device recited in claims 1, 17, 35 and 53.

Response to Arguments

Applicant's arguments filed November 11, 2004 have been fully considered but they are not persuasive.

In response to the applicant's argument regarding the objection to the specification, the examiner disagrees with the applicant's position. As previously stated, the applicant has support for the fact that the composition may be ingested by an infant, however, the fact that the composition is suitable for ingestion in the terms that the applicant is trying to define "suitable" has not been fully supported by the originally filed disclosure. The term "suitable" has been defined as "qualified" or "able" by Webster's Ninth New Collegiate Dictionary. The examiner agrees that according to this definition, the applicant may claim that the composition is "suitable" for ingestion. However, the applicant attempts to equate the term "suitable" to "safe", but this argument is not commensurate with the scope of the claims. The passages cited to support this position merely reinforce the examiner's interpretation that the composition is "qualified" or "able" to be ingested. The degree of safety of the composition to the person ingesting it is a separate issue. The examiner contends that the applicant is not able to read such limitations as "not harmful" or "appropriate or meant for ingestion" into the term suitable because this interpretation is not supported by the originally filed disclosure. The

applicant argues that the compounds of Allen are not proper or right for ingestion as they could kill the baby, however, the applicant has not claimed a composition that would not kill a baby. A baby could, in fact, have just a severe of a reaction to omega-3 fatty acids if the baby is allergic to such. In this case, the same composition that the applicant has claimed as being "suitable" for ingestion would not be according to the applicant's own definition.

Words of a claim are generally given their ordinary and customary meaning, unless it appears from the written description that they were used differently by the applicant. Where an applicant chooses to be his or her own lexicographer and defines the terms with special meanings, he or she must set out the special definition explicitly and with "reasonable clarity, deliberateness, and precision" in the disclosure to give one of ordinary skill in the art notice of the change. See *Teleflex Inc. v. Ficosa North America Corp.*, 299F.3d 1313, 1325, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp v. Laitram Corp.*, 274F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP § 2111.01.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Buckley

discloses that lotion of any type as is commercially available to afford protection and healing to an individual's skin portion may be provided on the breast cup arrangement (col. 3, lines 26 – 35) and the composition of Allen promotes improvement of the skin as set forth in col. 7, line 64 to col. 8, line 6.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a composition that treats the outer layer of the skin, a composition that improves skin and nipple health during breast feeding or a composition that can be safely ingested by a suckling infant) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The applicant's arguments are directed toward limitations that have not have been recited in the claims. The claimed invention is directed to a breast pad including a composition comprising omega-3 fatty acids. Buckley discloses a breast pad that may be impregnated with any commercially available lotion (col. 3, lines 31 – 35) and Allen discloses a breast treatment composition that includes omega-3 fatty acids.

The intended use of the claimed invention (i.e. topical application vs. ingestion) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference

as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Further, the examiner finds that the applicant's arguments are not commensurate with the scope of the claims. All compositions are suitable for ingestion. Whether or not the composition may be safely ingested is a separate argument that is not supported by the originally filed disclosure. See MPEP 21122 which states:

> In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald,* 964 F.2d 1122, 22 USPQ2d 1671 (Fed.Cir. 1992)

The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday - Friday, 5:30am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on 571-272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele Kidwell

Michele Kidwell
Examiner
Art Unit 3761